Section 1 D: SUMMARY OF SAFETY AND EFFECTIVENESS for the Access® Toxo IgM II assay

1. 0 General Information

Device Generic Name:	Enzyme Linked Immunoabsorbent Assay, *Toxoplasma Gondii*
Device Trade Name:	Access® Toxo IgM II Reagents for use on the Access® Immunoassay Systems
Device Class:	Class II
Applicant's Name and Address:	Beckman Coulter, Inc. Immunodiagnostics Development Center 1000 Lake Hazeltine Drive Chaska, MN 55318
Date:	October 13, 2000

2.0 Legally Marketed Device

The Access® Toxo IgM II Immunoassay

FDA 510(k) Number: K002453

3.0 Device Description

The Access® Toxo IgM II assay is a paramagnetic-particle chemiluminescent immunoassay for the qualitative detection of *Toxoplasma gondii*-specific IgM antibody in adult human serum, using the Access® Immunoassay Systems.

4.0 Principles of the Procedure

The Access Toxo IgM II assay is an immunoenzymatic assay and uses the immunocapture principle. The sample to be tested is added to a reaction vessel with paramagnetic particles coated with human IgM-specific sheep polyclonal antibody as capture antibody. After incubation in the reaction vessel, separation in a magnetic field and washing remove materials not bound to the solid phase. Then a complex formed with *T. gondii* (P30)-specific monoclonal antibody that has been labeled with alkaline phosphatase is added to the reaction vessel. After a second incubation and a second washing, a chemiluminescent substrate, Lumi-Phos530, is added and light generated by the reaction is measured with a luminometer. The photon production is a function of the amount of enzyme conjugate present at the end of the reaction. The light quantity measured for a sample allows a determination of the presence of *T. gondii*-specific IgM antibody, by comparison with a cut off value defined during the assay calibration on the instrument. If the light production is equal to or greater than the cut off value, the sample is considered reactive in the Access Toxo IgM II assay.

5.0 Indications for Use

The Access® Toxo IgM II assay is a paramagnetic-particle chemiluminescent immunoassay for the qualitative detection of *Toxoplasma gondii*-specific IgM antibody in adult human serum, using the Access® Immunoassay Systems. The Access® Toxo IgM II assay is presumptive for the diagnosis of acute, recent, or reactivated *Toxoplasma gondii* infections in males and pregnant or non-pregnant females. It is recommended this assay be performed in conjunction with an anti-*Toxoplasma gondii* IgG antibody assay.

6.0 Description of the Modification to the Legally Marketed Device

Extend the Indications for Use to include the measurement of plasma (EDTA, Citrate, Heparin) in the Access® Toxo IgM II assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 1 3 2001

Ms. Denise Thompson
Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

Re: 510(k) Number: K003259
Trade/Device Name: Access® Toxo IgM II Assay for use on the Access® Immunoassay System
Regulation Number: 866.3780
Regulatory Class: II
Product Code: LGD
Dated: April 11, 2001
Received: April 12, 2001

Dear Ms. Thompson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 1 C: **INDICATIONS FOR USE STATEMENT**

510(k) Number:

Device Name: Access® Toxo IgM II Reagents for use on the Access® Immunoassay Analyzer

Indications for Use:

The Access® Toxo IgM II assay is a paramagnetic-particle chemiluminescent immunoassay for the qualitative detection of *Toxoplasma gondii*-specific IgM antibody in adult human serum and plasma, using the Access® Immunoassay Systems. The Access® Toxo IgM II assay is presumptive for the diagnosis of acute, recent, or reactivated *Toxoplasma gondii* infections in males and pregnant or non-pregnant females. It is recommended this assay be performed in conjunction with an anti-*Toxoplasma gondii* IgG antibody assay.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003259

Prescription Use X OR Over-The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)